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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/616,766

07/09/2003

Roger O. Williams

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EXAMINER

HANDY, DWAYNE K

ART UNIT

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1797

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04/03/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/616,766	Applicant(s) WILLIAMS ET AL.
	Examiner DWAYNE K. HANDY	Art Unit 1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-142 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-142 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/13/03 & 8/25/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Interference

1. The request for interference filed 07/09/03 is acknowledged. However, examination of this application has not been completed as required by 37 CFR 41.102(a). Consideration of a potential interference is premature. See MPEP § 2303.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
3. Claims 10, 80 and 109 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 10, 80 and 109 contain the limitation "many thousands". Many is a relative term. It is unclear to the Examiner as to the number of thousands required to meet the limitation of "many thousands".

Inventorship

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 1-58, 66-131 and 137-142 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mutz et al. (2002/0061258). Mutz ('258) teaches a system and method of forming a microarray of compounds on a substrate using acoustic energy. The system is described in general in paragraphs [0035], [0058], [0059], [0063], [0064], [0069], and [0074]. It includes a plurality of reservoirs (13, 15) for holding ejected fluids, an acoustic ejector (33) having a focusing means (37), and a means (43) for positioning the acoustic ejector (33). Temperature control means is disclosed in

paragraph [0078]. Mutz teaches the use of microplates for the reservoirs in paragraphs [0035] and [0075]. The microplates may be standard 96, 384 or 1536 well plates but may also include up to 100,000 wells. Mutz discloses reservoir volumes in paragraph [0076]. The method of using the system to form an array is described in general in paragraphs [0036], [0069]-[0074] and [0082]-[0084]. The method includes the step of using an acoustic ejector (33) having a focusing means (37) to eject droplets of fluid from multiple reservoir wells (13, 15) to form an array of on a substrate (45). Mutz lists compounds – including biomolecules such as DNA, proteins, etc. - that may be used to form the array in paragraphs [0050]-[0056]. Mutz discloses the use of aqueous and non-aqueous fluids including organic solvents in paragraphs [0057] and [0076]. The use of acoustic waves to measure fluid height and other properties is taught in paragraphs [0090]-[0092]. Mutz ('258) does not specify an effective distance from the fluid height to the aperture and does not recite the f-value of the focusing means.

The Examiner submits that the choice of effective distance between the fluid height to the aperture to set the ratio of the effective distance to aperture width and choice of f-value for the focusing lens would be an optimization of the focusing means through routine experimentation. See MPEP 2144.05, IIA. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

In addition, the effective distance from the fluid height to the aperture would also be an obvious difference in relative dimensions between the instant device and the prior

art. See MPEP 2144.04, IV. In *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device.

7. Claims 1-18, 20-88 and 90-142 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mutz et al. (2002/0064808). Mutz ('808) teaches a system and method of forming a microarray of compounds or cells on a substrate using acoustic energy. The system is described in general in paragraphs [0006], [0013], [0014], [0031], [0032], [0042], [0045], and [0053]. It includes a plurality of reservoirs (13, 15) for holding ejected fluids, an acoustic ejector (33) having a focusing means (37), and a means (43) for positioning the acoustic ejector (33). Temperature control means is disclosed in paragraph [0058]. Mutz teaches the use of microplates for the reservoirs in paragraphs [0006] and [0055]. The microplates may be standard 96, 384 or 1536 well plates but may also include up to 100,000 wells. Mutz discloses reservoir volumes in paragraph [0056]. The method is described in general in paragraphs [0007], [0044]-[0045] and [0067]. The method includes the step of using an acoustic ejector (33) having a focusing means (37) to eject droplets of fluid from multiple reservoir wells (13, 15) to form an array on a substrate (45). Mutz lists compounds – including biomolecules such as DNA, proteins, cells etc. - that may be used to form the array in

paragraphs [0025]-[0029] and [0050]-[0056]. Mutz discloses the use of aqueous and non-aqueous fluids including organic solvents in paragraphs [0030] and [0056]. The use of acoustic waves to measure fluid height and properties is taught in paragraphs [0069] and [0070]. Mutz ('808) does not specify an effective distance from the fluid height to the aperture and does not recite the f-value of the focusing means. Mutz ('808) also does not specify droplet size.

The Examiner submits that the choice of effective distance between the fluid height to the aperture to set the ratio of the effective distance to aperture width and choice of f-value for the focusing lens would be an optimization of the focusing means through routine experimentation. See MPEP 2144.05, IIA. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

In addition, the effective distance from the fluid height to the aperture would also be an obvious difference in relative dimensions between the instant device and the prior art. See MPEP 2144.04, IV. In *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device.

Re: Droplet size – claims 59-65 and 132-136: Mutz is silent with respect to droplet size. Mutz, however, does disclose the size of sample diameter required for various analytical methods that are used with their array methods (paragraph [0100]). It would have been obvious to one of ordinary skill in the art, then, to provide a droplet having a size that would cover the area required for the desired analytical test. This would include the sizes recited by Applicant in claims 59-65 and 132-136.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DWAYNE K. HANDY whose telephone number is (571)272-1259. The examiner can normally be reached on M-F 8:00-4:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DKH
March 29, 2008

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797